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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,562	10/24/2003	Jukka T. Salonen	0933-0216P	8782

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EXAMINER	
SLOBODYANSKY, ELIZABETH	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,562	SALONEN ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky, PhD	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 15* is/are withdrawn from consideration.

5)☒ Claim(s) *11* is/are allowed.

6)☒ Claim(s) *10 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending.

Election/Restrictions

Applicant's election with traverse of Group V, claims 10-12, 14 and 13 (in part) in the reply filed on April 14, 2006 is acknowledged. The traversal is on the ground(s) that there is no undue burden placed on the Examiner to search and consider claims 1-15 in their entirety. At the very least the Examiner should search and consider the claims of Groups II-V together since the claims of these groups are all classified by the Examiner in class 435. Thus, no undue burden exists" (Remarks, page 2).

This is not found persuasive because these inventions of Groups I-V are distinct, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups. While Groups II and IV are classified in class 435, this is the most comprehensive class/subclass that is indicated. The search of each of the Groups II and IV requires search of classes/subclasses that are not required for Group V. For example, Group II requires search of 435/197 and Group IV of 435/18 that are not required for Group V.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups I-IV, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 14, 2006.

Claim Objections

Claim 13 is objected to as dependent from non-elected claim 9.

Appropriate correction is required.

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 depends from claim 10 that is drawn to an assay that analyzes a sample of DNA. As reciting the same claim 13 is not limiting the scope of claim 10.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connect ed, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10, with dependent claim 13, is drawn to a method for determining the presence in a biological sample of a DNA encoding Ile102Val mutation in a paraoxonase gene (PON1). The genus of paraoxonase genes comprises genes from various animals. The specification and the art teach human PON1 gene of SEQ ID NO: 3 encoding SEQ ID NO: 4. The art teaches that serum paraoxonase has been purified from several mammals but only human and rabbit PON1 proteins have been extensively characterized (Watson et al. (March 2001) Pharmacogenetics, Vol. 11, pages 123-134, especially page 123, 2nd column, last paragraph).

However, the specification fails to describe the correlation between structure and function common to the members of the genus of modulators suitable for BRET any structural features commonly possessed by members of the genus that distinguish them from other molecules, including other peptide linkers.

This recitation of the genus of PON1 fails to provide a sufficient description of the claimed genus of proteins as it merely describes the functional features of the genus without providing any definition of the structural features of the species within the genus. The CAFC in *UC California v. Eli Lilly*, (43 USPQ2d 1398) stated that: "In claims to genetic material, however a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA", without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do

with a fully described genus, visualize or recognize the identity of the members of the genus". Similarly with the claimed genus of PON1, the functional definition of the genus and subgenera does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the genus or subgenus from other proteins such that one can visualize or recognize the identity of the members of the genus or subgenus.

Claims 12 and 14 are rejected under 35 U.S.C. 1 12, first paragraph, because the specification, while being enabling for a method for assessing an individual's risk to develop cancer, coronary or cerebrovascular disease, hypertension, type 2 diabetes, dementia, arthrosis, cataract and individual's sensitivity to organophosphorus compounds, does not reasonably provide enablement for a method for assessing the effectiveness of an agonist and paraoxonase inducing or enhancing therapies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir., 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior ad, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the

claims.

The specification teaches that an individual having Ile102Val mutation in PON1 has an increased risk to develop cancer, coronary or cerebrovascular disease, hypertension, type 2 diabetes, dementia, arthrosis, cataract and has altered sensitivity to organophosphorus compounds (pages 9-14). However, the specification does not teach any agonists or paraoxonase inducing or enhancing therapies. Thus, the specification does not present guidance as to what are said agonists or therapies.

Therefore, one of ordinary skill in the art would require guidance beyond that provided, in order to asses the risk of an unknown PON1 agonist and an unknown therapies in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is confusing as reciting what appears to be several independent methods in one claim. The 1st method is drawn to assessing the risk and the other methods are drawn to the effectiveness of agonists and therapies.

Claim 14 does not have the antecedent basis for "the DNA" on line 1. Claim 14 is confusing because the metes and bounds of neither "DNA" or "an amplification product" or "an immobilized nucleic acid" are defined.

Allowable Subject Matter

Claim 11 is allowed.

Conclusion

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Salonen et al. (Oct 23, 2001) Supplement II Circulation, Vol. 104, No. 17, abstract 3794 (from PTO-1449 filed 10/24/03) describes Ile102Val mutation as a predictor of cardiovascular death. It is published after the effective filing date of this application.

Marchesani et al. (June 4, 2003) Journal of the National Cancer Institute, Vol. 95, No. 11, pages 812-818, describes the increased risk of prostate cancer in men having Ile102Val mutation in PON1. It is published after the effective filing date of this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

June 11, 2006